REMARKS

Upon entry of the present amendment, claims 1-19 are pending in the instant application. Claims 3-5, 18, and 19 have been withdrawn from consideration, subject to a restriction requirement. Elected claims 1, 2, 16, and 17, directed to a method of treating and/or preventing cerebral ischemia resulting from ***apoplexy*** (and not ***cardiac infarction*** as suggested in the Office Action of July 27, 2007) using a peritoneal solution containing hydrogenation products of frankincense extracts, stand rejected on non-reference grounds only.

Regarding the amendments presented herein:

In accordance with the Examiner's suggestion, the title has been amended to read: "A Method of Treating Cerebral Ischemia with Hydrogenation Products of Frankincense Extracts". In this manner, the title more accurately reflects the subject matter presently claimed.

Claim 1 has been amended to read "A method of treating and/or preventing cerebral ischemia comprising the step of administering to a subject in need thereof a medicament comprising as an active ingredient a hydrogenation product of *Boswellia serrata* obtained through the catalytic hydrogenation of ethanol extracts of frankincense (*Boswellia serrata*)." Support for this amendment is found in the specification as originally filed, for example at p. 8, lines 14-22, and p. 11, lines 16-24. This amendment is presented purely for the purposes of expediting prosecution and should not be interpreted as Applicants' agreement with the Examiner's position.

Claim 2 has been amended to read "The method according to claim 1, wherein the cerebral ischemia occurs as a result of apoplexy." Support for this amendment is found in the specification as originally filed. This amendment is presented purely for the purposes of expediting prosecution and should not be interpreted as Applicants' agreement with the Examiner's position.

Applicants respectfully submit that no new matter has been added. Moreover, Applicants respectfully submit that the instant response renders moot the outstanding objections and places the instant application in condition for allowance. Further to this position, Applicants submit the following remarks:

Rejections under 35 U.S.C. § 112, Second Paragraph

The Examiner rejected claim 1, 2, 16, and 17 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter regarded as the invention. In particular, the Examiner asserts that the metes and bounds of claim 1 are uncertain because the common name ingredients give rise to multiple interpretations. Furthermore, the Examiner finds the phrase "hydrogenation products of frankincense extracts" to be unclear.

The test for indefiniteness is whether one of ordinary skill in the art would understand the metes and bounds of the claim, when read in light of the specification and in the context of the prior art. Thus, claim language cannot be analyzed in a vacuum but must be interpreted in light of the specification, the teachings of the prior, and the reasonable interpretation given by one of ordinary skill.

In this case, Applicants respectfully submit that one skilled in the art would understand the metes and bounds of the phrase "hydrogenation products of frankincense extracts" as the preparation of extracts of such plants and methods for manufacturing hydrogenation products of such extracts are well known in the art. In support of this assertion, Applicants direct the Examiner's attention to the published U.S. patent application to Banerjee et al., US 2005-0192251, a copy of which is provided herewith, which discloses a process for the extraction of *Boswellia serrata* using standard extraction methods. Furthermore, the introductory portion, paragraphs [0002] to [0007], cites to various scientific articles that describe or refer to extracts of *Boswellia* gum resin. Accordingly, Applicants respectfully submit that the preparation of frankincense extracts, particularly ethanol extracts of *Boswellia serrata*, was known as of the filing date of the instant application.

Applicants also direct the Examiner's attention to the published international patent application to Gerke et al., WIPO No. WO02/15916, a copy of which is provided herewith, which refers to hydrogenated extracts of *Boswellia*, thereby confirming Applicants contention that the preparation of extracts of *Boswellia* as well as the hydrogenation of such extracts was conventional in the art as of the filing date of the instant application. See WO02/15916: abstract. WO02/15916 further discloses that extracts of gum resin of *Boswellia* (for example the

commercially available products Sallaki® and H15®) were known in the art as useful in the context of the treatment of inflammatory diseases.

Nevertheless, in an effort to expedite prosecution, Applicants have herewith amended claim 1 to refer to "a hydrogenation product of *Boswellia serrata* obtained through the catalytic hydrogenation of ethanol extracts of frankincense (*Boswellia serrata*)". Applicants respectfully submit that the claims so amended meet the threshold requirements for clarity and precision set forth in 35 U.S.C. § 112, second paragraph. As such, Applicants respectfully request reconsideration and withdrawal of the outstanding rejections of claim 1, 2, 16, and 17 under 35 U.S.C. § 112, second paragraph in view of the amendments and remarks herein.

Rejections under 35 U.S.C. § 112, First Paragraph - Enablement

The Examiner rejected elected claims 1, 2, 16, and 17 under 35 U.S.C. § 112, first paragraph, for failing to comply with the enablement and written description requirements. In particular, the Examiner asserts that, given the breadth of the claims, the lack of guidance provided, and the level of unpredictability in the art, the skilled artisan would have required an undue amount of experimentation to make and/or use the claimed invention.

It is important to note that a specification is presumed to be in compliance with the enablement requirement of 112, first paragraph. The burden is on the Patent Office to establish a reasonable basis to question enablement. The test of enablement is whether one reasonably skilled in the art could "make and use" the claimed invention from the disclosures in the patent coupled with information known in the art without undue experimentation. For an Examiner to sustain a rejection on the grounds of enablement, she must provide evidence that the claimed method could not be performed without undue experimentation. Applicants respectfully submit that the Examiner has not met this burden.

For example, on the issue of "how to use", Applicants note that much of the Examiner's concern relates to treating and preventing cerebral ischemia occurring as a result of ***cardiac infarction***. See Office Action, pp. 9-10. However, Applicants wish to remind the Examiner that the elected invention relates to Species A, "a method of treating or preventing cerebral ischemia

resulting from ***apoplexy***". See Applicants' Response of March 30, 2007, particularly p. 7, line 4-5. Accordingly, Applicants submit that evidence allegedly establishing the unpredictability of post-infarction ischemia is not relevant to the presently claimed invention.

Furthermore, for an Examiner to sustain a rejection on the grounds of enablement, he or she must provide evidence, and not mere conjecture or supposition, that the claimed invention could not be performed, for any purpose, without undue experimentation. See M.P.E.P. § 2164, particularly § 2164.01 and 2164.05. However, the fact that experimentation may be complex does not necessarily make it undue, particularly if the art typically engages in such experimentation. *In re Certain Limited-Charge Cell Culture Microcarriers*, 221 USPQ 1165, 1174 (Int'l Trade Comm"n 1983), *aff'd. sub nom., Massachusetts Institute of Technology v. A.B. Fortia*, 774 F.2d 1104, 227 USPQ 428 (Fed. Cir. 1985). See also *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404. In other words, the test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. *In re Angstadt*, 537 F.2d 498, 504, 190 USPQ 214, 219 (CCPA 1976). There are many factors to be considered when determining whether the specification is enabled and whether any necessary experimentation is "undue". Most importantly, the test for undue experimentation is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed.

In this case, the Examiner concludes that, given "the lack of guidance provided by the specification as well as the unpredictability in the art", one skilled in the art would be incapable of performing the claimed invention without undue experimentation. However, Applicants respectfully submit that it is not necessary to "enable one of ordinary skill in the art to make and use a perfected, commercially viable embodiment" in order to comply with 35 U.S.C. 112, first paragraph. *CFMT, Inc. v. Yieldup Int'l Corp.*, 349 F.3d 1333, 1338, 68 USPQ2d 1940, 1944 (Fed. Cir. 2003). In fact, detailed procedures for making and using the invention are not necessary if the description of the invention itself is sufficient to permit those skilled in the art to make and use the claimed invention, bearing in mind that a patent need not teach, and preferably omits, that which is well known in the art. As noted above, it is generally not necessary to describe each and every

parameter, such as dosage, route and method of administration, with specificity if such detailed information is either known to one skilled in the art or could be readily obtained without undue experimentation. In other words, if one skilled in the art, based on knowledge of compositions having similar physiological or biological activity, would be able to discern an appropriate dosage or method of use without undue experimentation, this would be sufficient to satisfy 35 U.S.C. 112, first paragraph. To that end, Applicants again direct the Examiner's attention to the Gerke (WO02/15916) and Banerjee et al. (US 2005/0192251) references which describe the use of the *Boswellia* extracts Sallaki® and H15® for the treatment of inflammatory diseases, thereby establishing that medicinal formulations of frankincense extracts were known in the art at the time of invention. See WO02/15916: p. 1, line 31 to p. 2, line 1; US 2005/0192251: paragraph [0003].

As for the Examiner's challenge to scope of Applicants' working examples, Applicants respectively submit that the *in vivo* studies described herein confirm the utility of frankincense extracts in the connection with the treatment of apoplexy. As noted in the instant specification, particularly at p.10, hydrogenation products of frankincense extracts have improved resorbance and are able to adequately penetrate the blood-brain barrier so that an adequate active substance concentration can be achieved in the target organ, the activity of the products being substantially maintained, even favorably improved. However, like other derivatives, such as salts and metabolites, hydrogenated forms of a base compound typically retain many of the characteristics of the base compound. Thus, physiological activities observed in a base compound may be reasonably extrapolated and attributed to hydrogenated forms thereof. Accordingly, since there is no reason to expect a hydrogenated form of a frankincense extract to react differently from the extract itself, Applicants respectfully submit that the positive results observed in the course of the *in vivo* examples of the instant specification support the operability and enablement of the instantly claimed invention.

On the issue of "how to make" the instantly claimed hydrogenation products, Applicants again direct the Examiner's attention to the Gerke reference (WO02/15916) discussed in detail above. According to WO02/15916, hydrogenation products of *Boswellia* extracts can be obtained using conventional processes known to those skilled in the art, for example via catalytic

hydrogenation. See WO02/15916: p. 6, paragraphs 2 and 6. See WO02/15916: p. 1, line 31 to p. 2, line 1. In addition, WO02/15916 teaches that heterogenous or homogenous hydrogenation can be used; examples of catalysts mentioned as suitable for heterogenous hydrogenation include Platinum, Palladium, and Rhodium whereas the Wilkinson-catalyst is mentioned as suitable for homogenous hydrogenation. See WO02/15916: p. 7, paragraphs 1 and 2.

Thus, for the reasons given above, Applicants respectfully submit that one of ordinary skill in the art would be able to both make and use the invention of the pending claims without undue experimentation. Accordingly, Applicants request reconsideration and withdrawal of the enablement rejection in view of the amendments to the claims and the remarks herein.

Rejections under 35 U.S.C. § 112, First Paragraph - Written Description

The Examiner further rejected elected claims 1, 2, 16, and 17 under 35 U.S.C. § 112, first paragraph, for failing to comply with the written description requirements. In particular, the Examiner challenges the specification for failing to provide an adequate definition for the term "hydrogenation products of frankicense extracts". Thus, she concludes that a skilled artisan would not recognize from the disclosure that Applicants were in possession of the entirety of the genus of "hydrogenation products of frankicense extracts".

The standard for determining compliance with the written description requirement is "does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed." *In re Gosteli*, 872 F.2d 1008, 1012, 10 U.S.P.Q.2d 1614, 1618 (Fed. Cir. 1989). The standard for determining sufficiency of the description is "factual and depends on the nature of the invention and the amount of knowledge imparted to those skilled in the art by the disclosure." *In re Wertheim*, 541 F.2d at 262 (citing *In re Ruschig* 379 F.2d 990, 995-96 (C.C.P.A. 1967)).

It is well accepted that a specification may, within the meaning of 35 U.S.C. 112, first paragraph, contain a written description of a broadly claimed invention without describing all species that the claim encompasses. The law does not require that the specification describe the exact details for preparing each and every species within the genus described. In fact, even if the

Examiner considers the subject matter of the claims to be broader than that disclosed in the original specification, the written description requirement may be satisfied if the broader concept would naturally occur to one skilled in the art upon reading the earlier specification.

In this case, solely in an effort to expedite prosecution, Applicants have amended claim 1 to read "A method of treating and/or preventing cerebral ischemia comprising the step of administering to a subject in need thereof a medicament comprising as an active ingredient a hydrogenation product of *Boswellia serrata* obtained through the catalytic hydrogenation of ethanol extracts of frankincense (*Boswellia serrata*)." Applicants submit that one skilled in the art could not only routinely obtain such products but would be further capable of identifying members of this genus. Accordingly, Applicants respectfully submit that the instant specification provides an adequate written description of the claimed genus of hydrogenation products so as to convey with reasonable clarity to those skilled in the art that, as of the filing date sought, Applicants were in possession of the invention now claimed.

CONCLUSION

The outstanding Office Action set a three-month shortened statutory period for response. Pursuant to the entry of Applicants' petition for a two month extension of time, response is due on or before **December 27, 2007**. Accordingly, Applicant submits that this response is timely and that no additional fee is required. However, in the event that further fees are required to enter the instant response and/or maintain the pendency of this application, the Commissioner is authorized to charge such fees to the undersigned's Deposit Account No. **50-2101**.

If the Examiner has any questions or concerns regarding this communication, she is invited to contact the undersigned.

Respectfully submitted,

Date: December 21, 2007

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